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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,724	12/08/2003	Antonius Arnoldus Christiaan Jacobs	I 1999.452 US C1	5481

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EXAMINER	
KAUSHAL, SUMESH	
ART UNIT	**PAPER NUMBER**
1633	

MAIL DATE	DELIVERY MODE
12/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/731,724	Applicant(s) JACOBS ET AL.	
	Examiner Sumesh Kaushal	Art Unit 1633	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 November 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *01 November 2007*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *6-28*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

SUMESH KAUSHAL, PH.D.
PRIMARY EXAMINER

Sumesh Kaushal
Primary Examiner
Art Unit: 1633

Continuation of 5. Applicant's reply has overcome the following rejection(s): Double Patenting Rejection: (TD over 6,682,745 and 6,120,775 filed). Claim objection (claim 28).

Continuation of 11. does NOT place the application in condition for allowance because: Claims 21-28 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (NEW MATTER ISSUES) for the reason of record as set forth in the office action mailed on 06/01/07. The applicant argues that newly filed claims 21-28 are supported by the specification through pages 1-3. However, applicant's argument is found not persuasive because the specification clearly states that "Systemic application comprises all applications in which the vaccine is NOT applied to the mucosa (mucosal application comprises i.e. oral and intranasal vaccination). Therefore the systemic administration of vaccines via sumucosa route of administration is NOT supported by the specification as filed. Since no basis has been found to support the new claim limitation in the specification, the claims are rejected as incorporating new matter.

Claims 6-28 are rejected under 35 U.S.C. 112, first paragraph, regarding i) WRITTEN DESCRIPTION and ii) ENABLEMENT issues for the reason of record as set forth in the office action mailed on 06/01/07. The applicant argues that applicant's discovery is applicable to all live attenuated vaccines independent of the bacterial strain or method of attenuation. The applicant argues that in view of the specification that teaches four different live bacterial strains and in view of state of the live attenuated bacterial vaccine art the invention as claimed meets the written description requirements. Regarding enablement issues the applicant argues that all live attenuated vaccine can be deliverd via submucosal administration without undue experimentation. However the applicant's arguments are found not persuasive because the method as claimed requires the possession of the product(s) that has not been fully described in the specification as filed, especially considering the full scope of invention that requires the use of ANY live attenuated vaccine obtained from "Actinobacillus equili, A. pleuropneumoniae, Actinomyces pyoyenes, Botdetella bronchiseptica, Brucella abortus, Clostridium perfringens, Corynebacterium bovis, C pseudotuberculosis, Erysipelotrix rhusioipathiae, Escherichia coli, Haemophilus parasuis, Leptospira canicola, L. hardjo, L icterohaemorrhagiae, L. poriona, Mycobacterium bovis, Mycoplasma bovis, M. hyopneumoniae, Noccatdia asteroides, Pasteurella haemolytica, P. multocida, Pseudomonas mallei, Rhodococcus equi, Salmonella cholerasuis, S. dublin, S. typimurium, Serpulina hyodysenteriae, Staphylococcus aureus, Streptococcus agalactiae, St. pneumoniae, St.suis, or St. uberis". The applicant fails to establish that they are in the possession of the product to be used (entire genus) in the method as claimed (see Written Description rejection). Furthermore, considering the unpredictability in the bacterial vaccine art, the specification as filed fails to provide any guidance regarding how to make the product to be used (genus as claimed) especially for the methods as claimed (see Enablement rejection). As stated earlier the disclosure of a single species is rarely, if ever, sufficient to describe a broad genus, particularly when the specification fails to describe the features of that genus, even in passing. Therefore, the limited disclosure in the specification is not deemed sufficient to reasonably convey to one skilled in the art that the applicants were in possessions of the huge genera recited in the claims at the time the application was filed, for the method as claimed The state of the art clearly teaches that understanding of regulatory pathways that affect bacterial virulence and protective antigens that provides long-term immune protection are consider germane to the development of a live attenuated bacterial vaccine. (see Curtiss R. J. Clin. Invest. 110(8):1061-1066, 2002, Tiball et al Vaccine 19:4175-4184, 20001, ref of record). Even though instant specification discloses only Streptococcus equi based attenuated strains (TW 928 and TW928/sls) the disclosure is considered insufficient, since the specification fails to disclose how to attenuate of any other species of bacteria that can be used as a vaccine without any adverse reaction (see enablement issues how to make/use). Since the sub mucosal injection of ANY live attenuated bacterial strain as vaccine is not considered routine in the art and without sufficient guidance to a specific bacterial strain and "vaccination outcome" base upon the immune protection the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir,1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See Ex parte Singh, 17 USPQ2d 1714 (BPAI 1991). Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed.

Claims 21-28 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the reason of record as set forth in the office action mailed on 06/01/07. The applicant fails to address this rejection in the remarks filed on 11/01/07.